

Message Text

UNCLASSIFIED

PAGE 01 STATE 028054

13-11

ORIGIN HEW-06

INFO OCT-01 ARA-10 EUR-12 EA-09 ISO-00 OES-05 EB-07 COME-00

/050 R

DRAFTED BY DHEW/FDA:JRWEINROTH, MD:AMS

APPROVED BY OES/APT/BMP:MBEAUBIEN

DHEW/OIH:MACODDING

ARA/CAR:DASTRASSER (INFO)

EA/J:DFSMITH (INFO)

ARA/PAN:JPBECKER (INFO)

ARA/APU:RCFELDER (INFO)

ARA/CEN:PWWACHERBARTH (INFO)

ARA/MEX:GFALK (INFO)

EUR/NE:SWORREL (INFO)

ARA/NC:TWSONANDRES

----- 055889

R 050131Z FEB 76

FM SECSTATE WASHDC

TO AMEMBASSY BUENOS AIRES

AMEMBASSY SANTO DOMINGO

AMEMBASSY TEGUCIGALPA

AMEMBASSY TOKYO

AMEMBASSY MEXICO

AMEMBASSY PANAMA

AMEMBASSY LONDON

AMEMBASSY CARACAS

UNCLAS STATE 028054

E.O. 11652: NA

TAGS: OGEN ETRD TBIO AR DR HO JA MX PN UK VE

SUBJ: SUBSTANDARD TENSILE STRENGTH SURGICAL SUTURES -
(VOLUNTARY RECALLS D-181-184/6 AND D-191-6)

1. FDA ADVISES THAT:

UNCLASSIFIED

UNCLASSIFIED

PAGE 02 STATE 028054

PRODUCTS INVOLVED:

A. D-181-6: ITEM NO. 1263 - DAVOL MARLEX BRAIDED SUTURES, LINEAR POLYETHYLENE MONOFILAMENT U.S.P. SIZE 2. SIX 54" SUTURE LENGTHS PER PEEL-BACK ENVELOPE. STERILE. DAVIL INC., PROVIDENCE, R.I. 12 ENVELOPES PER BOX.

B. D-182-6: ITEM NO. 1264 - CONTAINS THREE PEEL-BACK ENVELOPES OF ITEM 1263. DAVOL/USHERS MARLEX MESH. 6 M/L MONOFILAMENT KNITTED POLYPROPYLENE 1" X 4". FOR REPAIR OF INGUINAL HERNIAS. STERILE. DAVOL, INC., PROVIDENCE, R.I.

C. D-183-6: ITEM NO. 1266 - CONTAINS FOUR PEEL-BACK ENVELOPES OF ITEM 1263. DAVOL/USHERS MARLEX MESH. 6 M/L MONOFILAMENT KNITTED POLYPROPYLENE 10" X 14". FOR REPAIR OF LARGE VENTRAL HERNIAS, ABDOMINAL AND CHEST WALL DEFECTS. STERILE. DAVOL, INC., PROVIDENCE, R.I.

D. D-184-6: ITEM NO. 1267 - CONTAINS THREE PEEL-BACK ENVELOPES OF ITEM 1263. DAVOL/USHERS MARLEX MESH. 6 M/L MONOFILAMENT KNITTED POLYPROPYLENE, TWO PIECES 2" X 12" FOR REPAIR OF INCISIONAL HERNIAS. STERILE. DAVOL, INC., PROVIDENCE, R.I.

E. D-191-6: ITEM O. 1280 DAVOL/USHERS MARLEX TRACHEAL MESH - SPECIAL HEAVY POLYETHYLENE MONOFILAMENT MESH - FOR TRACHEAL RECONSTRUCTION 6" X 6" - WITH BRAIDED MARLEX SUTURES NO. 1263 U.S.P. SIZE 2. DAVOL INC., PROVIDENCE, R.I.

LOT NUMBERS:

ALL LOT NUMBERS OF DAVOL MARLEX BRAIDED SUTURES LINEAR POLYETHYLENE MONOFILAMENT U.S.P. SIZE 2 AND DAVOL MARLEX MESH PRODUCTS INCLUDING THE DAVOL BRAIDED SUTURES NO. 1263 U.S.P. SIZE 2.

MANUFACTURER:

SUTURES - ASHAWAY LINE AND TWINE CO.
ASHAWAY, RHODE ISLAND

MARLEX MESH - FABRICS DEVELOPMENT INC.
PHILADELPHIA, PENNSYLVANIA
UNCLASSIFIED

UNCLASSIFIED

PAGE 03 STATE 028054

RECALLING FIRM:

DAVOL, INC.
CRANSTON, R.I. 02910

REASON FOR RECALL: THE SUTURES, STERILE, NONABSORBABLE, SIZE NO. 2 ITEM NO. 1263 FAILED TO MEET U.S.P. XIX SPECIFICATIONS

FOR TENSILE STRENGTH. THE FIRM HAS RECEIVED COMPLAINTS CONCERNING BREAKING OF THE SUTURES. TESTS MADE BY THE FIRM CONFIRM THAT THE SIZE 2 SUTURES DO NOT COMPLY WITH THE U.S.P. XIX FOR TENSILE STRENGTH.

2. ON DECEMBER 24, 1975 THE FIRM, DAVOL, ISSUED A LETTER TO ALL DISTRIBUTORS STATING "ON OCTOBER 28, 1975 WE WROTE YOU REQUESTING THAT YOU RETURN ALL NO. 1263 MARLEX SUTURES, SINCE WE HAVE DECIDED TO DISCONTINUE THIS PRODUCT BECAUSE THE TENSILE STRENGTH DID NOT MEET U.S.P. REQUIREMENTS. IN ADDITION TO MARLEX SUTURES NO. 1263, THIS RECOVERY PROGRAM IS NOW EXTENDED TO INCLUDE ALL MARLEX MESH NO. 1264, NO. 1266, NO. 1267, NO. 1280, PACKAGED WITH SUTURES, OF ANY STERILE LOT NUMBER. ALTHOUGH THE MARLEX MESH IS PERFECTLY ACCEPTABLE, THESE BOXES ALSO INCLUDE NO. 1263 SUTURES WE WISH TO RECOVER. MARLEX MESH MARKED "WITHOUT SUTURES" SHOULD NOT BE RETURNED." RETURNS OF REQUESTED SUTURES AND MESH WITH SUTURES ARE TO BE DIRECTED TO:

DAVOL INCORPORATED
RETURN GOODS DEPARTMENT - MARLEX
ATTENTION: J. LIAL
69 POINT STREET
PROVIDENCE, RHODE ISLAND 02901

3. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO DETERMINE IF THEY HAVE RECEIVED LETTER OF DECEMBER 24, 1975 OR INFORMATION CONTAINED IN SAID LETTER. ANY QUESTIONS CONSIGNEES MAY HAVE REGARDING THIS ADVISORY SHOULD BE DIRECTED TO DAVOL, INCORPORATED.

4. FOREIGN CONSIGNEES AS FOLLOWS:

RECALL NO. D-181/4-6
UNCLASSIFIED

UNCLASSIFIED

PAGE 04 STATE 028054

1. FARMICIA REX S R L
CORDOBA 2401
BUENOS AIRES
ARGENTINA

2. LABORATORIOS ROLDAN C. POR A.
APARTADO POSTAL 1094
SANTO DOMINGO
REPUBLICA DOMINICANA

3. DISTRIBUIDORA DE EQUIPOS MEDICOS
5A CALLE 12
AVENIDA NO. 412
TEGUCIGALPA

HONDURAS C.A.

4(A) SUMITOMO BAKELITE CO., LTC.
DOWA BUILDING
2-22, 7-CHOME, GINZA
CHUO-KU, TOKYO 104
JAPAN

(B) YUFO ITONAGA CO., LTD.
19-11, 2-CHOME
TAKENOZUKA, ADACHI-KU
TOKYO, JAPAN

5. HARRY MAZAL, S.A.
ROMA 19
MEXICO 6, D.F.

6. LACASA DEL MEDICO
APARTADO 1689
PANAMA 1, REPUBLICA DE PANAMA

7. DAVOL INTERNATIONAL LTD.
VALLEY BRIDGE ROAD
CLACTON-ON-SEA
ESSEX, ENGLAND

UNCLASSIFIED

UNCLASSIFIED

PAGE 05 STATE 028054

8. COLIMODIO S.A.
ESTE 2Y SUR 21 NO. 128
APARTADO 1053
CARACAS, VENEZUELA

RECALL NO. D-191-6

1. LABORATORIOS ROLDAN C. POR A.
APARTADO POSTAL 1094
SANTO DOMINGO
REPUBLICA DOMINICANA

2. SUMITOMO BAKELITE CO., LTD.
DOWA BUILDING
2-22, 7-CHOME, GINZA
CHUO-KU, TOKYO 104, JAPAN
INGERSOLL

UNCLASSIFIED

NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL EQUIPMENT, CONSUMER PROTECTION, RECALLS
Control Number: n/a
Copy: SINGLE
Draft Date: 05 FEB 1976
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1976STATE028054
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, MD:AMS
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Film Number: D760043-0932
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1976/newtext/t19760278/aaaacqnc.tel
Line Count: 218
Locator: TEXT ON-LINE, ON MICROFILM
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 4
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Review Action: RELEASED, APPROVED
Review Authority: ElyME
Review Comment: n/a
Review Content Flags:
Review Date: 09 JUN 2004
Review Event:
Review Exemptions: n/a
Review History: RELEASED <09 JUN 2004 by BrownAM>; APPROVED <10 DEC 2004 by ElyME>
Review Markings:

Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
04 MAY 2006

Review Media Identifier:
Review Referrals: n/a
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
Secure: OPEN
Status: NATIVE
Subject: SUBSTANDARD TENSILE STRENGTH SURGICAL SUTURES - (VOLUNTARY RECALLS D-181-184/6 AND D-191-6)
TAGS: OGEN, ETRD, TBIO, AR, DR, HO, JA, MX, PN, UK, VE
To: BUENOS AIRES
MULTIPLE
Type: TE
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 04 MAY 2006